Application No.: 10/576,794 Docket No.: REGIM 3.3-093

IN THE CLAIMS

1. (currently amended) A pharmaceutical composition comprising a Wvirally-safe plasma-derived Factor VIII composition, characterized in that it is obtained after obtained by filtering through a nanometric filter of nominal having a pore size of 1315+2 nm to 2523+2 nm, wherein the filtrate comprises the virally-safe plasma derived Factor VIII solution having a and in that its—von Willebrand Factor (vWF) content is—of 15 % or less of decamers and higher multimers.

- 2. (currently amended) The pharmaceutical Composition as inof claim 1, characterized in that wherein the titre reduction factor of a virus of having a size of 24 nm to 3027+3 nm is 4 log or more, preferably 5 log, advantageously 6 log as compared with the solution before filtration.
- 3. (currently amended) The Pharmaceutical composition as in either of claims 1, and 2which is in the form of an injectable solution via intravenous, intramuscular or subcutaneous route.
- 4. (currently amended) A Mmethod for testing the viral safety of a plasma-derived Factor VIII composition obtained by nanometric filtering, comprising a the step consisting of determining the residual content of high multimerisation vWF.
- 5. (currently amended) The Mmethod as inof claim 4, wherein a determination of the residual content—characterized in that the detection—of less than 15 % vWF decamers and higher multimers after nanometric filtration indicates that said composition is virally safe.
- 6. (currently amended) The Mmethod as inof claim 5, wherein a determination of the residual content characterized in that the detection of less than 15 % vWF decamers and higher

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multimers is correlated with a reduction factor of virus titre of at least 4 log.

- 7. (currently amended) A Mmethod for preparing a virally safe Factor VIII solution, the method comprising:
- _a_filtering <u>a solution step</u>_through nanometric filters having a <u>of nominal</u> pore size <u>of 1315+2 nm to 2523+2 nm; and</u>
- <u>an assaying the filtrate to determine the residual content</u>
 of high-multimerization vWF step of von Willebrand Factor (vWF)
 decamers and higher multimers.
- 8. (currently amended) The Mmethod as inof claim 7, characterized in that wherein the step of assaying the filtrate step consists of includes verifying that the content of vWF decamers and higher multimers is 15 % or less.
- 9. (currently amended) The Mmethod as inof claim 7, characterized in that wherein a vWF decamer and higher multimer content of 15 % or less indicates that the titre reduction factor of a virus of having a size of 24 nm to 3027+3 nm is 4 log or more, preferably 5 log or to about 6 log as compared with the solution before filtration.

10. (canceled)

- 11. (new) A pharmaceutical composition comprising virally-safe plasma-derived Factor VIII having a von Willebrand Factor (vWF) contents of about 15% of less or less decamers and higher multimers.
- 12. (new) The pharmaceutical composition of claim 11 for use in treating diseases related to blood coagulation.

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13. (new) The pharmaceutical composition of claim 12 for use in treating haemophilia.

- 14. (new) The pharmaceutical composition of claim 1, wherein the titre reduction factor of a virus having a size of 24 nm to 30 nm is 5 log as compared with the solution before filtration.
- 15. (new) The pharmaceutical composition of claim 1, wherein the titre reduction factor of a virus having a size of 24 nm to 30 nm is 6 log as compared with the solution before filtration.
- 16. (new) The method of claim 7, wherein a vWF decamer and higher multimer content of 15 % or less indicates that the titre reduction factor of a virus having a size of 24 nm to 30 nm is 5 log ore more, to about 6 log as compared with the solution before filtration.
- 17. (new) The method of claim 7, wherein a vWF decamer and higher multimer content of 15 % or less indicates that the titre reduction factor of a virus having a size of 24 nm to 30 nm is 6 log ore more, to about 6 log as compared with the solution before filtration.
- 18. (new) A pharmaceutical composition comprising a virally-safe plasma-derived Factor VIII having a von Willebrand Factor content of 15% or less of decamers and higher mutimers.